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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,428	03/19/2001	Magnus Hook	P06668US03/BAS	6490

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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	12

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

OFFICE

Office Action Summary	Application No.	Applicant(s)	
	09/810,428	HOOK ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *15-22, 27-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,23,26 and 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election

1. Applicant's election of Group I claims 1-14, 22-26 and 28-32 in Paper No 11 (6/25/02) is acknowledged. However, the office regrets the oversight made on restriction requirement in Paper NO 10 in including claims 22, 24, 25 and 28 in Group I. Claims 22, 24 and 25 depend from Claim 18, which is drawn to a method in Group V. It is proper to include claims 22, 24 and 25 in-group V. Similarly claim 28 depend from Claim 27, which is drawn to another method in Group VI. It is proper to include claim 28 in-group VI. Therefore, claims 22, 24, 25 and 28 are withdrawn from Group I. Claims 1-14, 23, 26 and 29-32 are under examination. Claims 15-22, 27-28 have been withdrawn from consideration.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) 60/225,402 filed on 08/15/2000, 60/189,968 filed on 03/17/2000, 60/19,370 04/25/2000 is acknowledged

Information Disclosure Statement

3. Information Disclosure Statement filed on 8/17/01 (Paper # 6) is acknowledged and a signed copy is attached to this Office action.

Double Patenting

4. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting

ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-14, 23, 26 and 29-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/813,820. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims of the instant application and those of copending Application No. 09/813,820 are drawn to antibodies that bind to collagen binding protein and prevent S.aureus infection. Monoclonal and polyclonal antibodies to SEQ.ID.NO: 4 of the copending application bind to amino acids 61-343 of the full length CNA protein and therefore it is obvious that these antibodies bind to CNA 19 peptide of the present application that contains amino acids 151-318 of the full length CNA protein and is within the collagen binding region. Further, the antibodies of the copending application are monoclonal and polyclonal antibodies and are used as pharmaceutical composition to treat S.aureus infection. Therefore, antibodies that bind to CNA 19 peptide read on the antibodies of co-pending application. Antibodies that bind to collagen binding region, amino acid 61-343 would also bind to a smaller CNA 19 peptide that contains amino acids 151-318. The co-pending application teaches monoclonal and polyclonal antibodies to SEQ.ID.NO: 4 inhibit the bacterial adhesion to collagen and thereby preventing S.aureus infection. However, the diagnostic kits comprising these antibodies are not taught in the copending application. An artisan of ordinary skill would have been motivated in applying the art disclosed by the prior art because these antibodies specifically bind to S.aureus CNA peptide and kits that contain the antibodies which recognize the S.aureus infection would help in diagnosing S.aureus infection conveniently and do not

require trained technical support since it comes with instructions to use. Kits were well known in the art for testing or diagnosing varieties of diseases. Instructions are printed matter which have been long been held to distinguish a claimed structure over the prior art only where the printed matter functions in cooperation with the structure. Here there is no such functional cooperation between the printed instructions and the kit's structural components. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to keep the antibodies as disclosed by the prior art in the form of a compact kit since kits are easy to transport and convenient to work in places (economically under developed countries) with less facilities.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-14, 23, 26 and 29-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S.Patent 6,288,214. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims of the instant application and those of Patent are drawn to antibodies that bind to collagen binding protein and prevent S.aureus infection. The disclosed antibodies to SEQ.ID.NO: 6 of the Patent bind to amino acids 30-531 of the full length collagen binding protein, CNA and therefore it is obvious that these antibodies bind to CNA 19 peptide of the present application that contains amino acids 151-318 of the full length CNA protein and is within the collagen binding region. Further, the antibodies disclosed in the patent are monoclonal and polyclonal antibodies and are used as pharmaceutical composition to treat S.aureus infection. Therefore, the instant claims drawn to antibodies that bind to CNA 19 read on the prior art antibodies that bind to collagen binding region (amino acid 30-531) would also bind to a smaller CNA 19 (amino acids 151-318) peptide. The prior art teaches monoclonal and

polyclonal antibodies to SEQ.ID.NO: 6 inhibit the bacterial adhesion to collagen and thereby preventing S.aureus infection. However, the prior art does not teach diagnostic kits comprising these antibodies.

An artisan of ordinary skill would have been motivated in applying the art disclosed by the prior art because these antibodies specifically bind to S.aureus CNA peptide and would be useful in diagnosing S.aureus infection. Kits containing these antibodies are convenient to work and do not require trained technical support since it comes with instructions to use. Kits were well known in the art for testing or diagnosing varieties of diseases. Instructions are printed matter which have been long been held to distinguish a claimed structure over the prior art only where the printed matter functions in cooperation with the structure. Here there is no such functional cooperation between the printed instructions and the kit's structural components. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to keep the antibodies as disclosed by the prior art in the form of a compact kit since kits are easy to transport and convenient to work in places with less facilities.

7. Claims 1-14, 23, 26 and 29-32 are also rejected under 35 U.S.C. 103(a) as being obvious over U.S.Patent 6,288,214

The applied reference has a common inventor (i.e., Hook.M) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37

CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The prior art teaches antibodies to SEQ.ID.NO: 6. These antibodies bind to amino acids 30-531 of the full length CNA protein and therefore it is obvious that these antibodies bind to CNA 19 peptide that contains amino acids 151-318 of the full length CNA protein and prevent S.aureus infection. Further, the antibodies taught by the prior art are monoclonal and polyclonal antibodies and are used as pharmaceutical composition to treat S.aureus infection. The prior art teaches monoclonal and polyclonal antibodies that bind to SEQ.ID.NO: 6, which inhibit the bacterial adhesion to collagen. The prior art monoclonal and polyclonal antibodies inhibit the bacterial adhesion to collagen, i.e., antibody capable of displacing S.aureus to collagen (see abstract, figures 5-7 and columns 15-19 and claims). Further the prior art teaches antibodies prevent S.aureus infection (i.e., antibody capable of displacing S.aureus to collagen, see figures 7- 8) and other related bacterial colonies (column 4, lines 45-50). Therefore, the disclosed antibodies are cross-reactive to S.epidermis. The prior art also teaches diagnostic kits comprising the antibodies (column 26). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the antibodies of the prior art because the antibodies disclosed specifically bind to collagen binding region (amino acids 30-531) would also bind to smaller CNA peptide that contains amino acids 151-318 and is within the collagen binding region. An artisan of ordinary skill would have been motivated to use the

antibodies disclosed because it would have helped in diagnosing and treating S.aureus or S.epidermis infections. The claimed invention is a prima facie obvious in view of Hook et al absent any convincing to the contrary.

Claim Rejections - 35 USC 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 -14, 23, 26 and 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 31 recite CNA 19 peptide and CNA protein respectively. It is not clear what are the metes and bound of CNA 19 peptide and CNA protein.

Claim 23 is vague in reciting "151-318". Does applicant intend to mean 151-318 amino acids?

Claim Rejections - 35 USC 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent,

or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1 -14, 23, 26 and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hook et al WO97/43314 20 November 1997 (20.11.1997).

Hook et al., disclose the 19,000 M collagen-binding domain from *Staphylococcus aureus*, also known as CNA-19. The 19kda protein contains the 168 amino acid long segments, specifically amino acids 151-318 of the protein that has appreciable collagen binding activity (page 3). Hook et al., disclose the preparation of immunological compositions such as anti-collagen binding protein (CBP) antibodies for diagnostic and therapeutic methods relating to the detection and treatment of infections caused by *S. aureus* and related gram-positive species (page 16). The antibody compositions are disclosed which bind to site-specifically altered proteins, and specific native and synthetically mutated CBP with domain specific epitopes within the CBPs (page 16). The antibodies have been developed to inhibit collagen binding to CBP and S.aureus binding to extracellular matrix in both in vitro and in vivo (page 26 and claims). Hence the antibodies are capable of displacing S.aureus bound to an extracelllar protein. The antibodies may be monoclonal, or polyclonal (page 26 and claims) and interact with collagen binding domain of a staphylococcal cna gene product (claim 1). Therefore, the antibodies could cross react with S.epidermis. The vaccine formulation are useful against streptococcal and staphylococcal infection (page 29). The therapeutic and diagnostic kits comprising CBP compositions include antibodies and labels (page 37-39). The administration of antibodies reactive with CBP to at-risk subjects will be effective for prophylaxis of and in the case of infected subjects for therapy of bacterial infections (page 17). Preferred animals to receive treatment include mammals and particularly humans (page 18). Also taught were

immunoassays for detection in ELISA plates, dot blots and western analysis (page 20). Exemplary samples include clinical samples of blood and serum (page 21). Also taught are methods for inhibiting bacterial adhesion to collagen (page 22). Therefore, in the absence of evidence to the contrary the disclosed antibodies against CNA19 can perform the same functions as recited by the instant claims and thus anticipated the claimed invention.

11. Claims 1, 3, 5, 7, 9, 10-12, 14, 23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Patti et al (Journal of Biological Chemistry. May 1995, Vol, 270. No 20, pages 12005-12011).

Patti et al disclose polyclonal antibodies raised against collagen binding MSCRAMMs. The polyclonal antibodies bind to CNA peptides (figure 1) and have been shown to inhibit collagen binding of S.aureus (figures 2 and 3). Since these antibodies inhibit the binding of S.aureus, these antibodies are capable of displacing S.aureus bound to collagen (pages 12007-12010). Antibodies suitable for administration of parenteral, oral etc for treating and preventing S. aureus are considered as intended use of these antibodies. . A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to an intended use must result in a manipulative difference as compared to the prior art. See In re Casey; 152 USPQ 235 (CCPA1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the prior art anticipates the claimed invention. . In the absence of evidence to the contrary the disclosed prior art antibodies and the claimed antibodies are same. Since the Office does not have the facilities for examining and comparing applicants' antibodies and with the antibodies of the prior art, the burden is on applicant to show a novel or unobvious

difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

12. Claims 1, 3, 5, 7-12, 14, 23, 26 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Patti et al (Journal of Biological Chemistry. May 1992, Vol, 267. No 7, pages 4764-4772).

Patti et al disclose monospecific (page 4766, right column 2nd paragraph) and polyclonal antibodies (see figure 4 legend) raised against native collagen from S.aureus (page 4766, right column 2nd paragraph). These anti-receptor antibodies bind to collagen (figure 7) and have been shown to inhibit collagen binding of S.aureus (figures 6). Since these antibodies inhibit the binding of S.aureus, these antibodies are capable of displacing S.aureus bound to collagen. Antibodies suitable for administration of parenteral, oral etc for treating and preventing S. aureus are considered as intended use of these antibodies. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to an intended use must result in a manipulative difference as compared to the prior art. See In re Casey; 152 USPQ 235 (CCPA1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Thus the prior art anticipates the claimed invention. In the absence of evidence to the contrary the disclosed prior art antibodies and the claimed antibodies are same. Since the Office does not have the facilities for examining and comparing applicants' antibodies and with the antibodies of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

13. Claims 1-14, 23, 26 and 29-32 are rejected under 35 U.S.C. 102(e) as being anticipated

by Hook et al 2001 (U.S.Patent 6,288,214).

The disclosed antibodies to SEQ.ID.NO: 6 of the Patent (see claims) bind to amino acids 30-531 of the full length CNA protein. Therefore, these antibodies bind to CNA 19 peptide of the present application that contains amino acids 151-318 of the full length CNA protein and prevent S.aureus infection. Further, the antibodies disclosed in the patent are monoclonal and polyclonal antibodies and are used as pharmaceutical composition to treat S.aureus infection (see abstract, figures 5-7 and columns 15-19). Further the prior art discloses antibodies that prevent S.aureus infection (i.e., antibody capable of displacing S.aureus to collagen, see figures 7- 8) and other related bacterial colonies (column 4, lines 45-50). Therefore, the disclosed antibodies are cross-reactive to S.epidermis. The prior art also discloses diagnostic kits comprising the antibodies (column 26).

Status of Claims

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

9/4/02

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